K100512

1.4 510(k) Summary of Safety and Effectiveness

AUG 20 2010

Submitted by:	Herbert Crane Director, Global Regulatory Affairs
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Date of Submission:	February 19, 2010
Classification Name:	Porcelain powder for clinical use (21 CFR 872.6660) Product code EIH
Trade or Proprietary or Model Name:	NobelProcera IPS e.max Crown
Legally Marketed Device(s):	Procera Copings and Pontic (K032562) IPS e.max CAD/IPS e.max Zircad (K051705)

Device Description:
NobelProcera IPS e.max CAD Crowns are core superstructures intended for the fabrication of crowns. They are made of lithium disilicate glass-ceramic using a wax-up or CAD design technique.

The Nobel Biocare IPS e.max CAD core superstructure can be designed using traditional wax-up technique or using Nobel Biocare crown design software. The core superstructure can be designed using the final anatomic shape or a cut-back technique. Wax-up designs are scanned at the laboratory. Both scanned wax-up and CAD designed core superstructure design information is transmitted electronically to the Nobel Biocare manufacturing facility. The core superstructures are manufactured using CAM techniques and delivered to the laboratory for finishing.

Indications for Use:
The NobelProcera IPS e.max Crown is indicated for use as core structures of crowns that will be cemented to natural or artificial tooth abutments in the treatment of partially edentulous patients as an aid in prosthetic rehabilitation.

Non-Clinical Testing
Nobel Biocare has performed mechanical testing of the e.max material including ageing, biaxial (ISO 6872), static, and dynamic load tests to ensure the product will be strong enough to withstand the anticipated mastication forces.

Clinical Testing
Non-clinical test data was used to support the decision of safety and effectiveness.

Conclusions
The testing indicates that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE
	NobelProcera IPS e.max Crown	Procera Copings and Pontic (K032562)	IPS e.max CAD/IPS e.max Zircad (K051705)
Anatomical Site	**- Oral Cavity**	- Oral Cavity	- Oral Cavity
Material	**- Lithium disilicate ceramic (IPS e.max CAD blocks)**	- Aluminum oxide - Zirconium oxide	- Lithium disilicate ceramic - Zirconium oxide
Indications for Use	**The NobelProcera IPS e.max Crown is indicated for use as core structures of crowns that will be cemented to natural or artificial tooth abutments in the treatment of partially edentulous patients as an aid in prosthetic rehabilitation.**	Nobel Biocare's Procera® Copings and Pontic are indicated for use as core structures of an artificial prosthesis, i.e. a three-unit bridge, for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. The Pontic is indicated as the core structure of the center unit and the Copings are indicated as the core structures of the two side crowns, thereby forming the three-unit bridge. - The Copings are also indicated for use as single crowns that will be cemented to a natural or artificial tooth abutment in the treatment of partially edentulous patients in order to restore chewing function.	IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges. IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays and 3- and 4-unit bridges and inlay bridges (anterior and molar).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K100512
Trade/Device Name: NobelProcera IPS e.max Crown
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical use
Regulatory Class: II
Product Code: EIH
Dated: July 27, 2010
Received: July 28, 2010

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100512

1.3 Indications for Use

510(k) Number (if known): K100512

Device Name: NobelProcera IPS e.max Crown

Indications For Use:

The NobelProcera IPS e.max Crown isindicated for use as core structures of crowns that will be cemented to natural or artificial tooth abutments in the treatment of partially edentulous patients as an aid in prosthetic rehabilitation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100512